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PATENT
Docket No.: 026549-000100US
Client Ref. No.: 30836

TOWNSEND and TOWNSEND and CREW LLP

By: 

Jo Ann Honcik Dallara

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Ronit Eisenberg

Application No.: 10/009,809

Filed: April 26, 2002

For: CELL PENETRATING ANTI-
ALLERGIC PEPTIDES

Customer No.: 20350

Confirmation No.: 1519

Examiner: Crowder (Dahle), Chun

Art Unit: 1644

REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

This Reply Brief is responsive to the Examiner's Answer mailed on
August 13, 2009.

In the previous papers, appellants have complained that the Examiner has not properly considered the evidence traversing the *prima facie* case of obviousness. In the Examiner's Answer, the Examiner now articulates her reasoning for ignoring appellants' evidence of surprising and advantageous results. This reasoning is not legally proper and demonstrates why the present obviousness rejection must be reversed.

The inventors wanted to deliver known mast cell inhibitor peptides into mast cells. To accomplish this delivery, they fused the inhibitors to a number of different cell penetrating peptides. This invention is the discovery that of the various cell penetrating peptides [CPP] tested, only the CPP from Kaposi fibroblast growth factor

[KFGF] was able to both penetrate the mast cells and deliver the inhibitors in an active form. This experimental observation was a surprising and unpredictable discovery and thus is deserving of patent protection. Two Rule 132 declarations attest to the surprising and unpredictable nature of the pending claims.

Despite the simplicity and classic nature of the above story of patentability, the Examiner refused to consider the evidence and maintained the rejection. On page 8 of the Examiner's Answer she explains:

The prior art of Lin et al. as well as appellant's own evidence consistently teach that the claimed peptide AAVALLPAVLLALLAP (SEQ ID NO: 3) is capable of not only transporting various peptides across cell membranes of different cell types, but is also able to retain the biological activities of the peptide it transports. **There is no evidence, either in prior art or the instant specification, showing that AAVALLPAVLLALLAP (KFGF) does not work.**

From the Examiner's own words, she concludes that the evidence of inoperability of the other CPPs is irrelevant because there is no evidence that the KFGF CPP would not work. This is an impossible standard to meet. The Examiner's approach reverses the initial evidentiary burden, placing it on the appellants and renders the *prima facie* case of obviousness virtually irrebuttable.

More specifically, the Examiner cannot arbitrarily focus on a single reference and ignore references that teach away from her conclusion. *Akzo N.V. v USITC*, 1 USPQ 2d 1240 at 1246 (CAFC 1986). None of the references disclosing individual cell penetrating peptides say their CPPs won't work with mast cell inhibitors. There is nothing special in the Lin et al. reference that says that CPP from KFGF works better than the other known CPPs.

By demanding proof that the KFGF CPP works poorly, she places an improper evidentiary burden upon the appellants. It is not appellants' responsibility to prove that

the KFGF CPP was *a priori* a poor agent for transporting mast cell inhibiting peptides. Rather, it is the Examiner's burden to prove that the KFGF CPP was a **superior** CPP! Absent that teaching, the Examiner must presume, as the inventors did, that *any* CPP would deliver the two mast cell inhibitors in an active form.

Finally, the Board is again reminded that both Examiners Nolan and Crowder initially held the art of cell penetrating peptides to be unpredictable and made §112 rejections. The quoted statements regarding the art speak for themselves.

To belatedly focus on the Lin reference in favor of the other CPPs and demand that the appellants prove that the KPGF CPP was considered by those of skill to be inferior to the other known CPPs, defeats the purpose behind the legal rubric of a *prima facie* case of obviousness. By reversing the initial evidentiary burden, the Examiner's reasoning renders the *prima facie* case of obviousness irrebuttable for all practical purposes. This is a clear error of law and the rejection should be reversed.

Respectfully submitted,



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